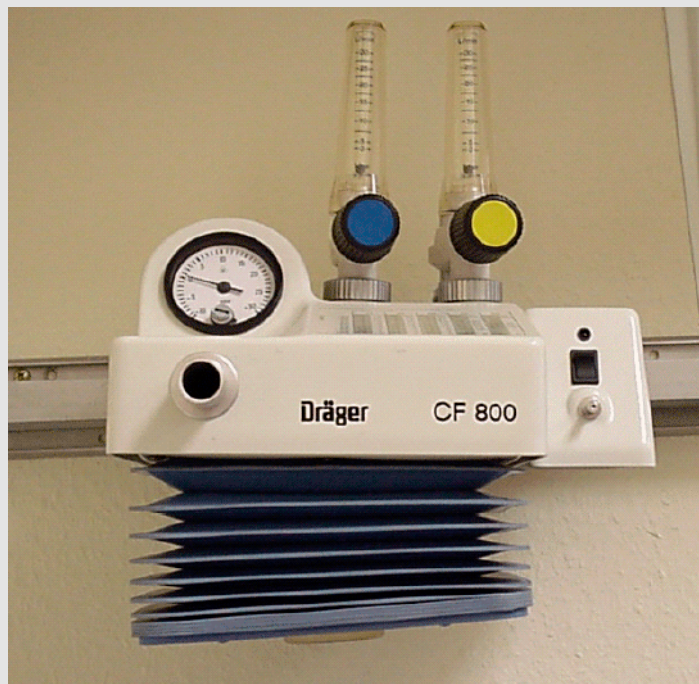


Technical Documentation

CF 800

for Continuous Flow CPAP Therapy



Revision 2.0
5682
9036076

General

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Function Description

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Test List

General

1 Notes

This Technical Documentation conforms to the IEC 60601-1 standard.

Read each step in every procedure thoroughly before beginning any test. Always use the proper tools and specified test equipment. If you deviate from the instructions and/or recommendations in this Technical Documentation, the equipment may operate improperly or unsafely, or the equipment could be damaged.

Use only original Dräger parts and supplies.

The maintenance procedures described in this Technical Documentation may be performed by qualified service personnel only. These maintenance procedures do not replace inspections and servicing by the manufacturer.

The information in this manual is confidential and may not be disclosed to third parties without the prior written consent of the manufacturer.



Strictly follow the Instructions for Use manual / Operating Instructions! This Technical Documentation does not replace the Instructions for Use manual / Operating Instructions. Any use of the product requires full understanding and strict observation of the product-specific Instructions for Use manual/ Operating Instructions.



Reference is hereby made to the observance of the relevant safety provisions, for example in Germany, the Medical Product Law (MPG), the Medical Device Operator Ordinance (MPBetreibV), the Pressure Container Ordinance (Druckbehälterverordnung), the Technical Rules for Pressurized Gases (Technische Regeln Druckgase), or the Occupational Health and Safety Provisions (Unfallverhütungsvorschriften).

Unless otherwise stated, reference is made to laws, regulations or standards (as amended) applicable in the Federal Republic of Germany.

Follow the laws and regulations applicable in your country.

1.1 Symbols and Definitions



This symbol indicates a warning.



This symbol indicates tips and useful information.



This symbol is used to alert against unsafe practices when handling electrostatic sensitive devices (ESD).

Definitions according to German standard DIN 31051:

Inspection	= examination of actual condition
Maintenance	= measures to maintain specified condition
Repair	= measures to restore specified condition
Servicing	= inspection, maintenance, and repair

Function Description

1 General

Air and O₂ pass via the filter 1 and 2 into the corresponding flowmeters with metering valve 3 and 4. With the aid of the reference list the required O₂ concentration is adjusted (with the proportion of the flow amount O₂: air). This flow fills the reservoir 5 and passes continuously via the non-return valve 6 to the inspiration output. The airway pressure is measured with the pressure gauge 7. The relief valve 8 limits the airway pressure in the system to max. 30 mbar. The necessary breathing volume for the inspiration is provided prior with the continuous flow. Inspiration flow for the patient comes from the reservoir 5. The non-return valve 6 stops a re-breathing into the reservoir 5. In case the medical compressed gas supply fails, ambient air is sucked in via the bypass air valve 9. A self-locking coupling 10 supplies the medicament nebulizer with compressed air.

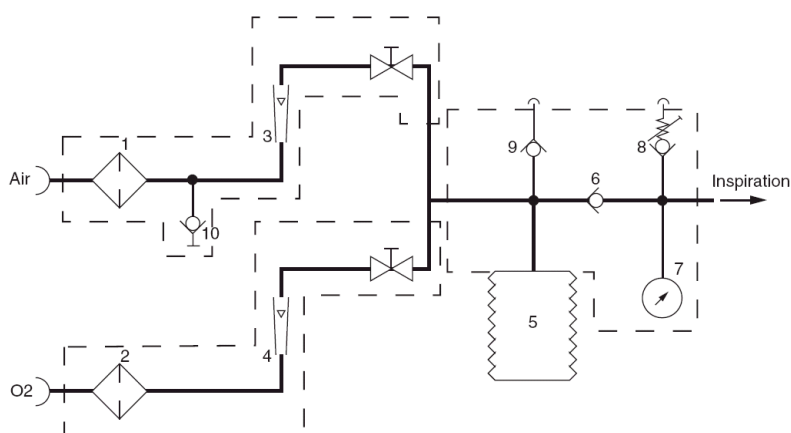


Figure 1 Function diagram

Table 1 Legend **Figure 1**

Pos.	Designation
1	Filter
2	Filter
3	Flowmeter with valve for air
4	Flowmeter with valve for oxygen
5	Reservoir (bellows)
6	Non-return valve
7	Pressure gauge
8	Relief valve
9	Bypass air valve
10	Coupling for medicament nebulizer

- 2Intended use
- CF800 is a device for the application of respiratory therapeutical measures with continuously positive airway pressure. The device should only be applied on patients with spontaneous breathing. The CPAP system CF 800 is a compact unit consisting of:
- Aquapor for the heating and humidifying of the breathing air
 - AWT 01 or thermometer for the temperature measurement
 - Oxydig for the inspiratory O2-measurement
 - Pneumatic medicaments nebulizer for medicaments nebulizing
 - PEEP valve to built up positive airway pressure (CPAP)
- 3Monitoring
- The device has no integrated monitoring. By recognition of insufficient spontaneous breathing or malfunction of the device (disconnection, gas failure, breaking of hoses) a regular visual check by authorized medical personnel is necessary. With the Oxydig the inspiratory O2-concentration is monitored. With the AWT 01 the inspiratory breathing air temperature is automatically monitored.

Weight	3,0 kg
Measurements:	Height = max. 550 mm Width = 212 mm Depth = 260 mm

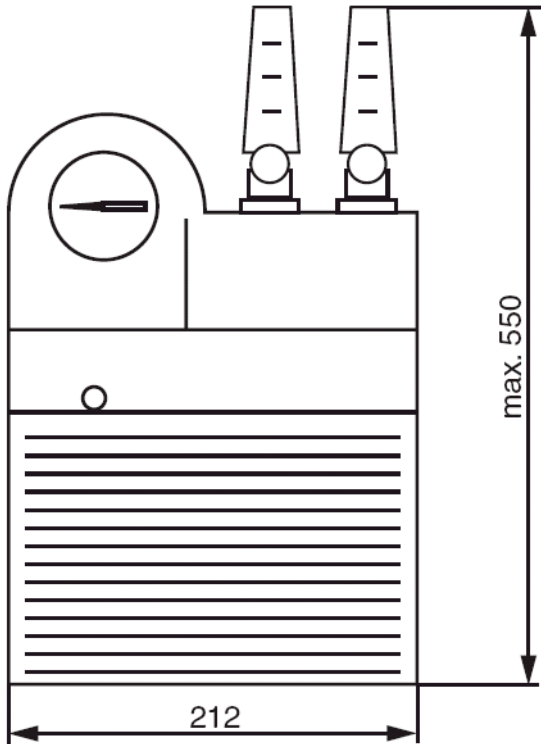


Figure 2 CF 800

Compliance of the reservoir	400 mL/mbar
Max. pressure variations at flow > 1.5 x volume per minute	+/- 2 mbar
Safety valve	limits the airway pressure to max. 30 mbar
Emergency air valve	opens at a low pressure of 0.4 mbar, makes it possible to go on with spontaneous breathing if the compressed air supply fails
Manometer for measuring the airway pressure	-10 to 30 mbar
error in measuring	2,5% of final value

Operating values

Gas supply	
O ₂ -pressure	2,7 to 6 bar
Connection thread	M12x1 innen
Air pressure	2,7 to 6 bar
Anschlussgewinde	M20x1,5 außen
	The gases must be dry, free of oil and dust
Gas consumption	corresponds to the set total flow
Noise during operation sound pressure acc. to DIN45635	max. 45 dB (A)

Annex

Parts catalog

Test List

Parts catalog

CF 800

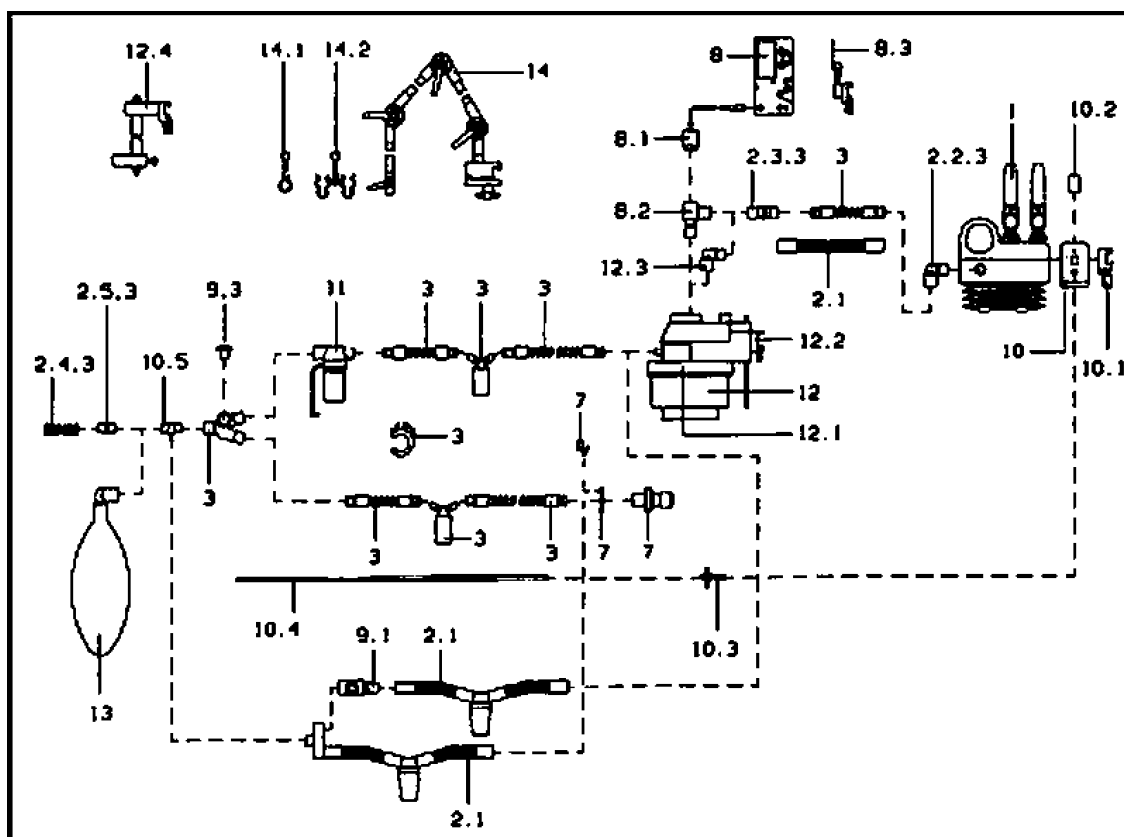
Revision: 2005-06

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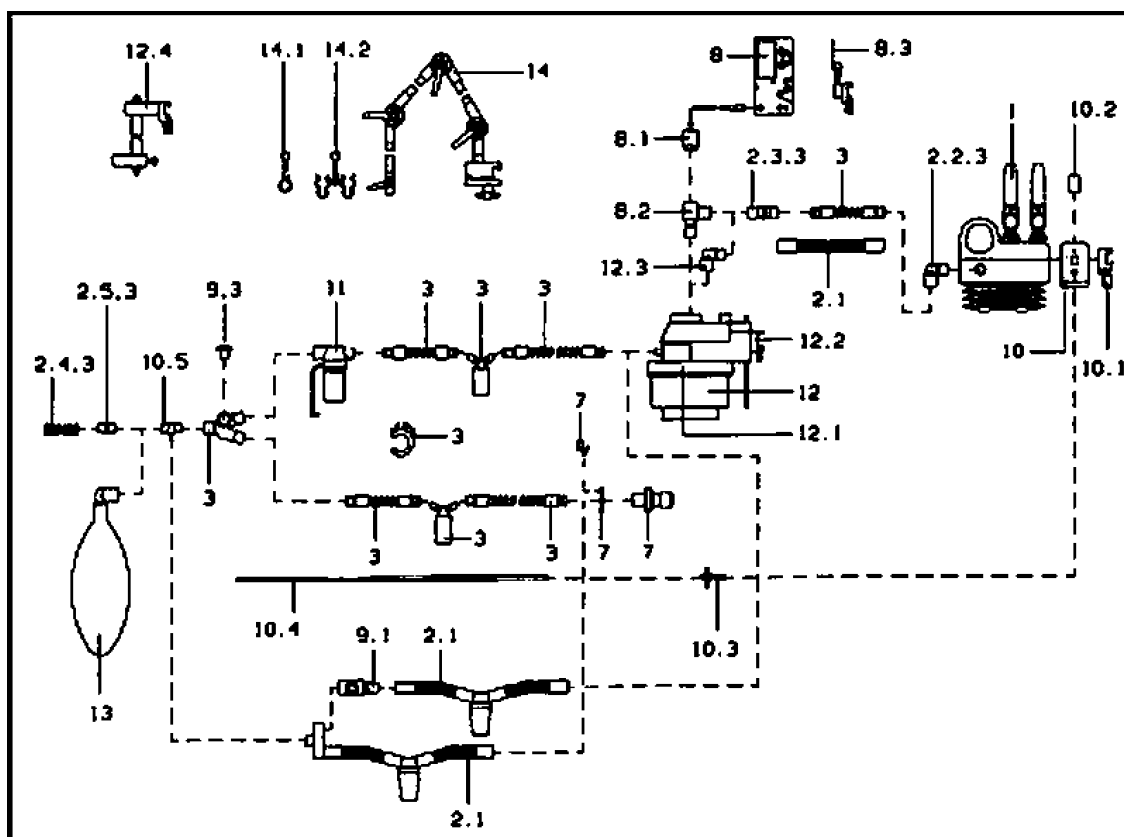
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
	8414300	CF 800	1.000	St	
	8409400	CF 800 (CPAP DEVICE)	1.000	St	
	8410130	CF 800 P (PAED. CPAP DEVICE)	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	8409400	CF 800 (CPAP DEVICE)	1.000	St	
2	8409645	ONE-WAY PATIENT CONNECTION	1.000	St	part 2.1; 2.2.3; 2.3.3; 2.4.3 and 2.5.3
2.1	8407571	HOSE SET, DISPOSABLE	1.000	St	
2.2.3	8290274	ANGLE SOCKET ISO	1.000	St	
2.3.3	M25647	NOZZLE 22/22	1.000	St	
2.4.3	8402041	CORRUGATED HOSE	1.000	St	
2.5.3	8403685	SET 12 STAND. CONE A PLASTIC	1.000	St	
3	8413146	HOSE SET E2 (BLUE)	1.000	St	
7	8409646	PEEP-VALVE WITH SUPPORT	1.000	St	
8	8304411	Oxydig complete	1.000	St	
9.1	8405791	SENSOR SLEEVE ADULTS	1.000	St	
9.3	2M13259	THERMOMETER	1.000	St	
10.1	M20650	Rail clamp	1.000	St	
10.2	1335812	ALCALI-BATTERY,9 V	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



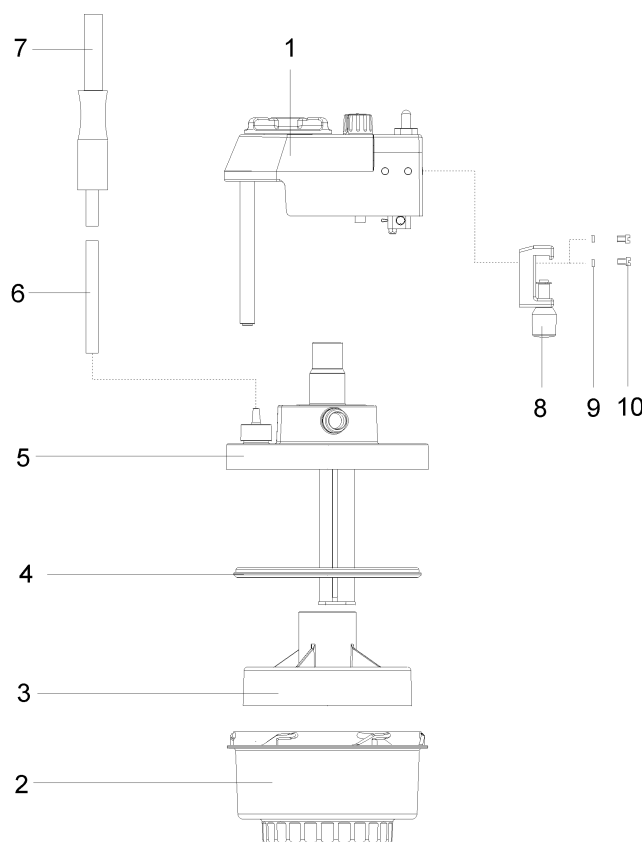
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
10.3	8402868	BACTERIA FILTER	1.000	St	
10.4	1190520	HOSE 4X1,5-SI 50 SH A NF	1.000	m	
10.5	8400904	TAPER ADAPTER	1.000	St	
11	8405000	MEDICAMENT NEBULIZER (PNEU)	1.000	St	
12.1	8405029	PATIENT PART (AQUAPOR)	1.000	St	
12.2	8403345	SET OF SPARE BRACKETS	1.000	St	
12.4	8409450	AQUAPOR SUPPORT FOR RAIL	1.000	St	
13	8403201	TEST LUNG	1.000	St	
14	8409609	HINGED ARM 240-DEGR.	1.000	St	
14.1	8409746	SUPPORT FOR HINGED ARM A	1.000	St	
14.2	8409841	HOSE CLAMP FOR HINGED ARM	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



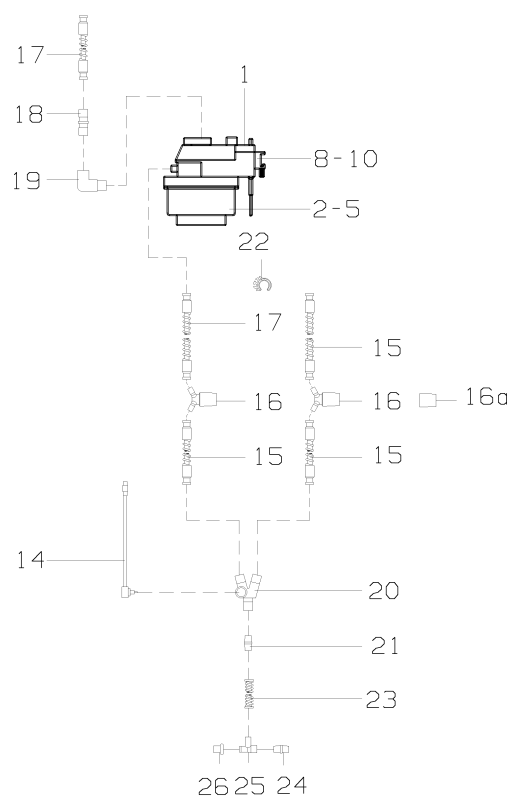
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
	8414700	Aquapor EL, Humidifier	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



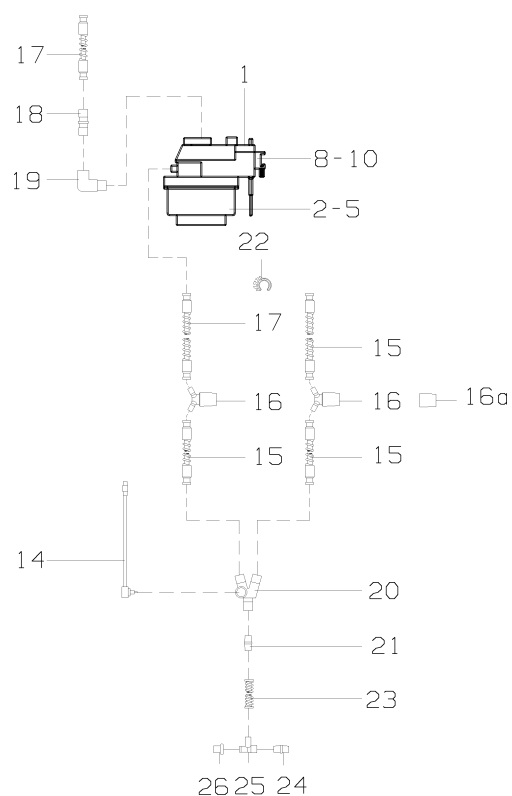
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	8414699	Heating Top	1.000	St	
1-5	8414700	Aquapor EL, Humidifier	1.000	St	
2	8404739	TROUGH	1.000	St	
2-5	8405029	PATIENT PART (AQUAPOR)	1.000	St	
3	8404738	FLOAT	1.000	St	
4	8404741	LIP SEAL	1.000	St	
5	8406135	REP.SET COVER (AQUAPOR)	1.000	St	
6	1190520	HOSE 4X1,5-SI 50 SH A NF	1.000	m	
6-7	8405031	FILLING KIT FOR AQUAPOR	1.000	St	
7	8405077	FUELLDORN,UGR.	1.000	St	
8	M20650	Rail clamp	1.000	St	
8-10	8403345	SET OF SPARE BRACKETS	1.000	St	
9	1300849	SPLIT WASHER B5 DIN127-X12CRNI	2.000	St	
10	1320440	SCREW AM5X16 DIN84	2.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



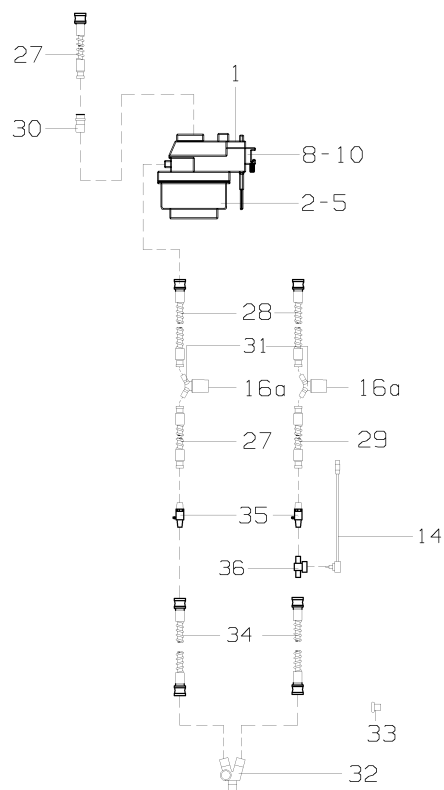
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	8414699	Heating Top	1.000	St	
2-5	8405029	PATIENT PART (AQUAPOR)	1.000	St	
8-10	8403345	SET OF SPARE BRACKETS	1.000	St	
14	8405371	TEMPERATURE SENSOR	1.000	St	
15	2165627	BREATHING HOSE E 60CM	3.000	St	
15-26	8412092	ADULT HOSE SET, AQUAPOR	1.000	St	
16	8404985	Water trap	2.000	St	
16A	8403976	POT	0.000	St	
17	8403367		2.000	St	
18	M25647	NOZZLE 22/22	1.000	St	
19	M25649	MASKENKRUEMMER	1.000	St	
20	8405435	Y-PIECE	1.000	St	
21	M23840	STANDARD CONN.12,5 PLASTIC	1.000	St	
22	8403566	TUBE CLAMPS	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



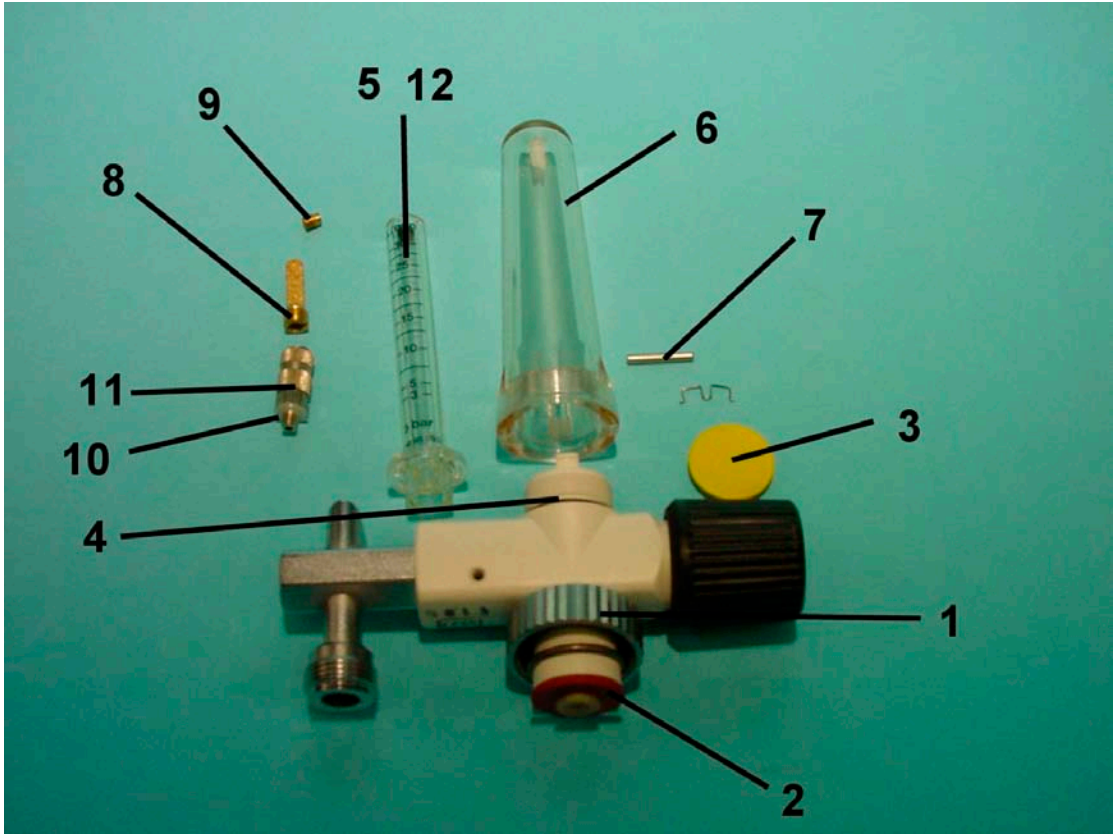
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
23	8402041	CORRUGATED HOSE	1.000	St	
24	8403685	SET 12 STAND. CONE A PLASTIC	12.000	St	different types from size 6 to 12
25	8403076	ADAPTER E	1.000	St	
26	8402918	SET OF 5 CAPS (8401644)	5.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



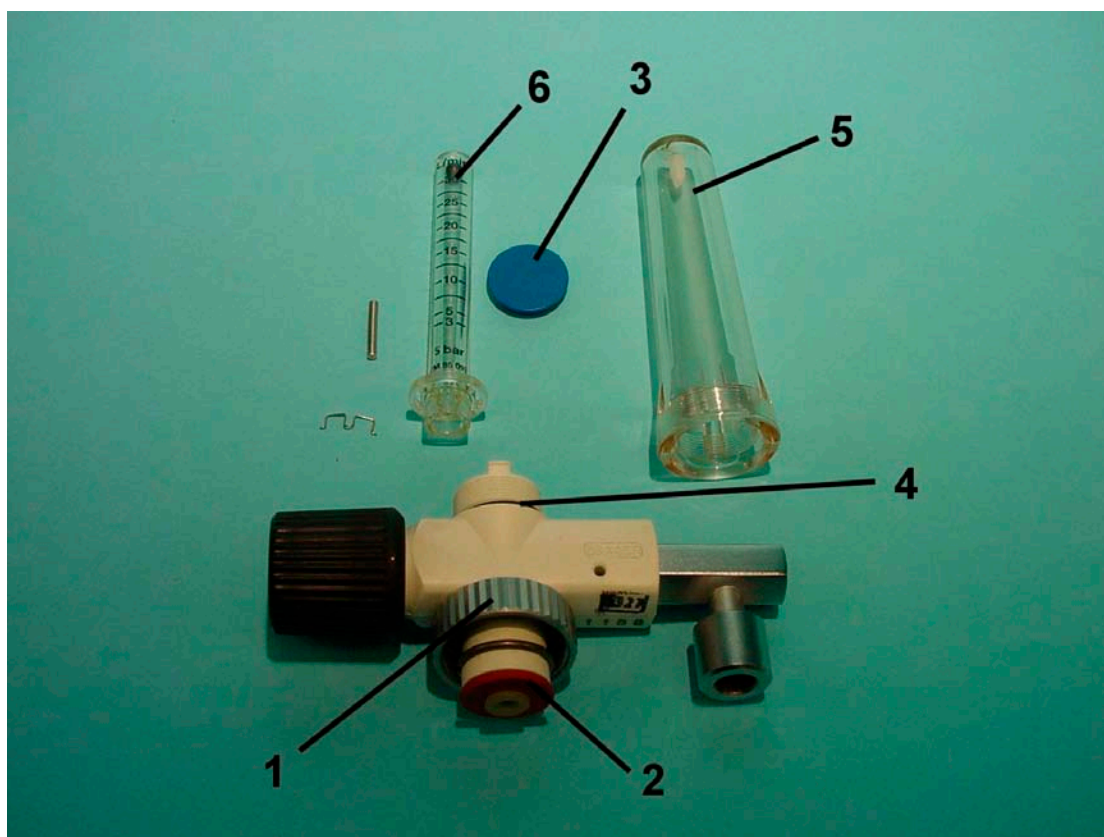
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	8414699	Heating Top	1.000	St	
2-5	8405029	PATIENT PART (AQUAPOR)	1.000	St	
8-10	8403345	SET OF SPARE BRACKETS	1.000	St	
27	2165856	BREATHING HOSE K 22/10 0,4M	2.000	St	
27-36	8412344	PAED HOSE SET, AQUAPOR	1.000	St	
28	2165848	BREATHING HOSE K 10/10 0,6M	2.000	St	
29	2165821	BREATHING HOSE K 22/10 0,6M	1.000	St	
30	8405752	CONE 22A	1.000	St	
31,16A	8409627	CONDENSATE TRAP EX.	2.000	St	
32	8403075	Y-PIECE 90DEGREE	1.000	St	
33	8401645	CAP (7 MM)	5.000	St	
34	8403333	CORRUGATED HOSE 140 MM	2.000	St	
35	8404760	STEAM TRAP	2.000	St	
36	8403056	ADAPTER FOR THERMOMETER	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1-11	8409452	FLOWMETER 30L/MIN, 5BAR	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1-5	8409445	O2 FLOWMETER 30L/MIN, 5BAR	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Assembly	Description	Part No.
Accessories Aquapor EL		
	Aquapor EL, Humidifier	8414700
	FILLING KIT FOR AQUAPOR	8405031
	FLOAT	8404738
	FUELLDORN, UGR.	8405077
	Heating Top	8414699
	HOSE 4X1,5-SI 50 SH A NF	1190520
	LIP SEAL	8404741
	PATIENT PART (AQUAPOR)	8405029
	Rail clamp	M20650
	REP.SET COVER (AQUAPOR)	8406135
	SCREW AM5X16 DIN84	1320440
	SET OF SPARE BRACKETS	8403345
	SPLIT WASHER B5 DIN127-X12CRNI	1300849
	TROUGH	8404739
Accessories/Consumables		
	ALCALI-BATTERY, 9 V	1335812
	ANGLE SOCKET ISO	8290274
	AQUAPOR SUPPORT FOR RAIL	8409450
	BACTERIA FILTER	8402868
	CF 800 (CPAP DEVICE)	8409400
	CORRUGATED HOSE	8402041
	HINGED ARM 240-DEGR.	8409609
	HOSE 4X1,5-SI 50 SH A NF	1190520
	HOSE CLAMP FOR HINGED ARM	8409841
	HOSE SET E2 (BLUE)	8413146
	HOSE SET, DISPOSABLE	8407571
	MEDICAMENT NEBULIZER (PNEU)	8405000
	NOZZLE 22/22	M25647
	ONE-WAY PATIENT CONNECTION	8409645
	Oxydig complete	8304411
	PATIENT PART (AQUAPOR)	8405029
	PEEP-VALVE WITH SUPPORT	8409646
	Rail clamp	M20650
	SENSOR SLEEVE ADULTS	8405791
	SET 12 STAND. CONE A PLASTIC	8403685
	SET OF SPARE BRACKETS	8403345
	SUPPORT FOR HINGED ARM A	8409746
	TAPER ADAPTER	8400904
	TEST LUNG	8403201
	THERMOMETER	2M13259
Basic Unit		
	CF 800 (CPAP DEVICE)	8409400

Assembly	Description	Part No.
Concerned Devices		
	Aquapor EL, Humidifier	8414700
Flowmeter Air		
	FLOWMETER 30L/MIN, 5BAR	8409452
Flowmeter O2		
	O2 FLOWMETER 30L/MIN, 5BAR	8409445
Heating Top		
	Heating Top	8414699
Hose Set Adults		
	ADAPTER E	8403076
	ADULT HOSE SET, AQUAPOR	8412092
	BREATHING HOSE E 60CM	2165627
	CORRUGATED HOSE	8402041
	Heating Top	8414699
	MASKENKRUEMMER	M25649
	NOZZLE 22/22	M25647
	PATIENT PART (AQUAPOR)	8405029
	POT	8403976
	SET 12 STAND. CONE A PLASTIC	8403685
	SET OF 5 CAPS (8401644)	8402918
	SET OF SPARE BRACKETS	8403345
	STANDARD CONN.12,5 PLASTIC	M23840
	TEMPERATURE SENSOR	8405371
	TUBE CLAMPS	8403566
	Water trap	8404985
	Y-PIECE	8405435
Hose Set Children Aquapor		
	ADAPTER FOR THERMOMETER	8403056
	BREATHING HOSE K 10/10 0,6M	2165848
	BREATHING HOSE K 22/10 0,4M	2165856
	BREATHING HOSE K 22/10 0,6M	2165821
	CAP (7 MM)	8401645
	CONDENSATE TRAP EX.	8409627
	CONE 22A	8405752
	CORRUGATED HOSE 140 MM	8403333
	Heating Top	8414699
	PAED HOSE SET, AQUAPOR	8412344
	PATIENT PART (AQUAPOR)	8405029
	SET OF SPARE BRACKETS	8403345
	STEAM TRAP	8404760
	Y-PIECE 90DEGREE	8403075

Assembly	Description	Part No.
Instructions For Use		
	GA-DISKONNEKTMONITOR D	9028681
	User manual Aquapor EL me	9037476
	User manual Aquapor EL me	9037567
Manuals/Techn.Documentation		
	IFU CF 800 DE/EN	9028679
	IFU CF 800 FR/ES	9028680
	IFU CF 800 IT/NL	9029214
	IFU CF 800 SV	9029215
Patient Part		
	PATIENT PART (AQUAPOR)	8405029
Power Cord Aquapor EL		
	Power cable 10A, 3m, grey, USA/J	1841793
	Power cable Australia 3m,10A,C13L	1844350
	Power cable DK, 3 m, 10 A	1844342
	Power cable Great Britian 3m black	1844369
	POWERCORD CH 3M	1844377
	SUPPLY MAIN, 3M	1824481
Products Concerned		
	CF 800	8414300
	CF 800 (CPAP DEVICE)	8409400
	CF 800 P (PAED. CPAP DEVICE)	8410130

Test List

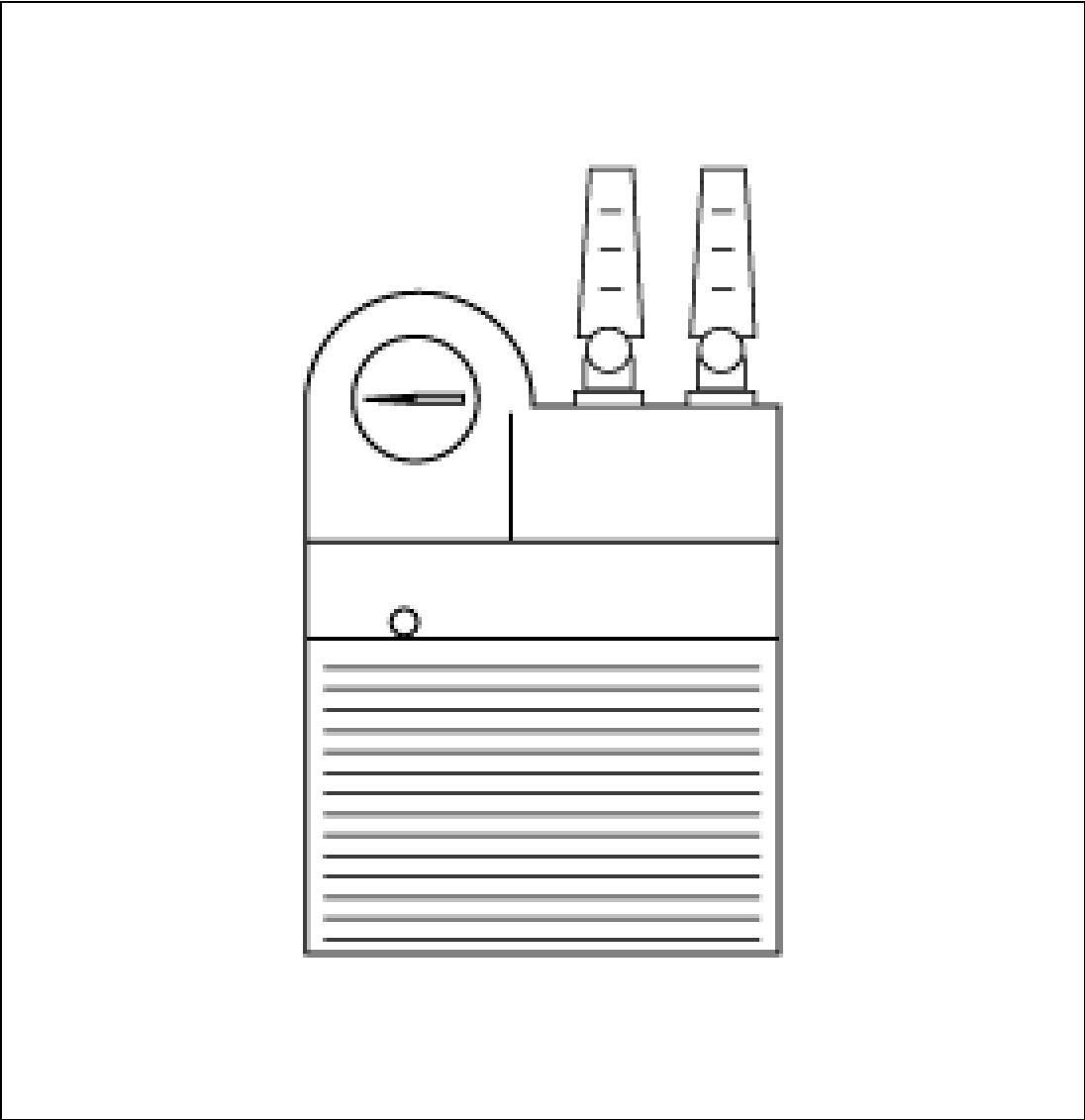
CF 800

Serial no.: _____

Installation site: _____

File no.:
5682

Edition:
05.00



1 Test equipment required for the Test List

Flowmeter 10 to 120 L/min	Class 1.6
Flowmeter 0.01 to 14 L/min	Class 1.6
Manometer -30 to +120 mbar	Class 1.6
Stopwatch	
Thermometer	
Test lung	

2 Accessories

2.1 Peripheral equipment

- Check the peripheral equipment according to the relevant Test List.

☐

2.2 Hinged arm

- Check the following elements for proper functioning and condition:
 - Rail clamp
 - Adjustability of brackets
 - Locking mechanism
 - Hose holder

☐☐☐☐

2.3 Patient tubes

- Check the following elements for proper functioning, tightness, and condition:
 - Water separator
 - Y-piece
 - Hoses (see Instructions for Use manual)

☐☐☐

2.4 Thermometer

- Perform a reference measurement using a thermometer.

Maximum deviation $\pm 2\text{ }^{\circ}\text{C}$

☐

2.5 Ambu PEEP valve

- Check the condition of the Ambu PEEP valve.

☐

3 Compressed-gas supply

3.1 Pipeline supply connecting tubes

- Check the condition and the tightness of the pipeline supply connecting tubes.

☐

3.2 Flowmeters

- Perform a reference measurement using an external flowmeter.
- Unscrew the flowmeter and connect the port to an external flowmeter.
- Check the readings at three different settings.

The permissible deviation for the lowest reading is $\pm 15\%$. For all other readings it is $\pm 10\%$.

O₂ readings

☐

AIR readings

☐

Fit the flowmeters.

3.3 Drug nebulizer supply

- Connect the drug nebulizer port to a flowmeter.

Reading 3.3 L/min $\pm 0.3\text{ L/min}$

☐

4 Functional test

4.1 Leak test

- Connect the outlet to a pressure gauge.
- Build up a pressure of 10 mbar.
- Close the flow-control valves.

The maximum permissible pressure drop within 1 minute is 1.5 mbar.

☐

4.2 Pressure gauge

Test set-up as in 4.1.

- Adjust different pressures and compare the readings on the internal and external pressure gauges.

The permissible tolerance between the pressure gauges is $\pm 2.5\%$ of the upper-range value.

☐

4.3 Safety valve

Test set-up as in 4.1.

- Adjust the flow to 20 L/min.

The bellows extend to its maximum length. The safety valve should open at $22 + 4$ mbar.

☐

4.4 Emergency air valve

- Connect the outlet to the test lung.
- Close the flow-control valves.
- Generate a negative pressure using the test lung.

The emergency air valve should open at 0 to -0.5 mbar.

☐

4.5 Non-return valve

Test set-up as in 4.4.

- Generate a negative pressure using the test lung, and then release the test lung.

The resulting reading may decrease by 5 mbar within 30 seconds.

☐

4.6 PEEP valve

- Assemble the unit ready for use and connect the test lung.
- Adjust the flow to 20 L/min.
- Check the PEEP at the following settings:

PEEP = 0, reading 0 +1.5 mbar

☐

PEEP = 10, reading 10 +1.5 mbar

☐

4.7 Spontaneous breathing

Test set-up as in 4.6.

- Simulate breathing.

Pressure fluctuations at the pressure gauge are ± 1.5 mbar.

☐

5 Handover

- Place fully functional unit at the user's/owner's disposal.

☐

Date: _____

Name: _____

Manufacturer:

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D-23542 Lübeck
Germany

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Directive 93/42/EEC
concerning Medical Devices

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